REMARKS

Prior to the instant amendment, Claims 61, 63-66, and 68-86 were pending for prosecution in this case. Claims 61 and 70-75 have been amended. The amendments to the claims do not constitute new matter and are believed to place the application in condition for allowance or, at a minimum, place the application in better form for appeal by materially reducing or simplifying the issues for appeal. Support for the amendments can be found at, for example, pages 6, 35 and 84-93 in the specification. Thus, entry of the amendment is respectfully requested. The Applicant notes that claims 76-83 and 86 are allowable.

Withdrawal of Objections and Rejections

The Applicant notes the Examiner's withdrawal of the objection to the drawings and figures under 37 C.F.R. §§ 1.58(a) and 1.83 in view of the Applicant's argument.

The Applicant also notes the Examiner's withdrawal of the following rejections of:

- claims 62 and 67, in view of the Applicant's cancellation of those claims;
- claims 61, 64-66, 68, 69, 72-74, and 76-83 under 35 U.S.C. § 112, second paragraph, as being indefinite, in view of the Applicant's amendment;
- claims 61, 63-66, and 68-75 under 35 U.S.C. § 112, first paragraph, as lacking enablement, in view of the Applicant's amendment; and
- claims 61, 63-66, and 68-75 under 35 U.S.C. § 112, first paragraph, as lacking written description, in view of the Applicant's amendment.

Formal matters

Claims

The Applicant has amended claims 61, 72, and 75, in line with the Examiner's suggestion in the last Office Action. Accordingly, claims 61, 63-66, 68, 69, and 84 should be allowable.

Title

In the previous amendment and response filed on January 16, 2007, the Applicant amended the title of the application, to comply with the Examiner's suggestion in the first Office

Action, to read as follows: "Pharmaceutical Compositions, Kits, and Therapeutic Uses of Antagonist Antibodies to IL-17E." However, the Examiner has not acknowledged the amended title in the subsequent Office Action. The Applicant respectfully requests that the Examiner make specific note that the objection to the title is removed in view of the Applicant's amendment.

Inventorship

The Examiner's acknowledgment of the change of inventorship is noted and reflected in the caption for this instant amendment and response.

Information Disclosure Statement

The Examiner's acknowledgement of her full consideration of the foreign patent documents listed on Form 1449, as submitted as part of an information disclosure statement filed on October 10, 2003, is noted.

Priority

In the previous amendment and response filed on January 16, 2007, the Applicant amended the priority claim for the instant application. In addition, the Applicant pointed out specific passages in the specifications of the earliest filed applications that contain disclosures that support the currently claimed subject matter. However, the Examiner has not acknowledged the amended priority claim in the subsequent Office Action. The Applicant respectfully requests that the Examiner note that the previous objection to the priority claim is removed in view of the Applicant's amendment.

Rejections under 35 U.S.C. § 112, second paragraph – indefiniteness

Claims 70 and 71 remain rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter. Specifically, the Examiner objects to the two claims for depending on a canceled claim, claim 67.

The Applicant believes that in light of the amendments to claims 70 and 71 to depend on claim 61, the indefiniteness rejection is moot and should be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph – new matter

Claims 73 and 74 remain rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. Specifically, the Examiner argues that a

> composition compris[ing] an immune stimulating or inhibiting molecule is in context to the composition of matter comprising a PRO polypeptide or an agonist or antagonist antibody, and it does not indicate a composition comprising the combination of a PRO polypeptide or an agonist or antagonist antibody *and* another immune stimulating or inhibiting molecule or immunosuppressant.

Office Action, p. 4 (emphasis in original). The Applicant respectfully disagrees with the Examiner's interpretation of the plain language and meaning of the paragraph at issue in the specification. However, in the interest of expediting the prosecution of the instant application, the Applicant has amended claims 73 and 74 to recite "a cytotoxic agent" as opposed to an "immune inhibiting molecule." The Applicant believes that in light of the amendment, the Examiner's new matter rejection should be withdrawn.

For example, the Applicant points to page 6 of the specification, and in particular, the paragraph from lines 4-16. The first sentence of the paragraph describes a composition comprising, *inter alia*, an antagonist antibody which binds a PRO polypeptide in admixture with a carrier or excipient. Furthermore, the penultimate sentence of the paragraph describes the composition which comprises a "further" or additional active ingredient, wherein the further active ingredient may be a further antibody or, for example, a cytotoxic agent. The Applicant believes that at least these aforementioned sentences in the specification provide ample support for claim 73.

In addition, the specification at page 35, lines 27-35 teach that the term "cytotoxic agent," includes, *inter alia*, chemotherapeutic agents, and that examples of chemotherapeutic agents include, *inter alia*, methotrexate. Thus, the Applicant believes this passage provides ample support for claim 74.

Accordingly, in light of the teachings of the specification, the Applicant believes that the new matter rejection of claims 73 and 74 is improper and should be withdrawn.

Rejection Under 35 U.S.C. § 102(e)

Claims 72, 75, and 85 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,562,578 by Gorman *et al.* (hereinafter referred to as "Gorman"). According to the Examiner, *In re Schoenwald*, 964 F.2d 1122, 22 U.S.P.Q.2d 1671 (Fed. Cir. 1992), supports the current § 102(e) rejection by holding – in a § 102(b) context – that utility need not be disclosed by the "prior art" reference in order for the publication to serve as anticipatory prior art. Office Action, p. 5. The Applicant again traverses the Examiner's rejection.

It is the Examiner's position that under "35 U.S.C. 102(e), an anticipating reference needs only to meet the requirement that 'the invention was described in (1) ... or (2) a patent granted on an application for patent'." *Id.* According to the Examiner, Gorman discloses the sequence for and how to make the IL-174 polypeptide and how to make the antibody thereto and therefore anticipates the currently rejected claims under § 102(e). *Id.* Moreover, the Examiner previously argued that because Gorman's IL-174 polypeptide, the amino acid sequence of which is disclosed in SEQ ID NO:14, "comprises about 90% of the present SEQ ID NO:6 with 100% sequence identity," Gorman's antibodies would bind to the present polypeptide of SEQ ID NO:6. Office Action mailed August 14, 2006, p. 9. "As such, one of ordinary skill in the art would be able to *make* (or synthesize) the polypeptide and the antibody thereto according to the teachings of the prior art reference." Office Action, p. 5.

The Applicant asserts that the Examiner's rejection suffers from both legal and factual errors. To be prior art under 35 U.S.C. § 102(e), the reference must meet, *inter alia*, the requirements of 35 U.S.C. § 112, first paragraph, *i.e.*, the written description and enablement requirements. The Examiner's conclusion that the claimed pharmaceutical compositions and kits, which comprise, *inter alia,* antagonist antibodies, are "well described" in Gorman is insupportable, as will be discussed below, because Gorman fails to: 1) establish a specific, substantial, and credible utility for the claimed subject matter; 2) teach one of ordinary skill in the art how to make pharmaceutical compositions or kits comprising, *inter alia,* an antagonist antibody to the disclosed human IL-174 molecule; and 3) show that its inventors were in

possession of pharmaceutical compositions or kits comprising, *inter alia,* an isolated antagonist antibody to the disclosed IL-174 molecule.[1]

A. A reference under 35 U.S.C. § 102(e) must teach how to make and use the claimed invention to be accorded prior art status.

Section 102(e) states "a person shall be entitled to a patent unless:

...

(e) the invention was described in –

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language."

Section 102(e) deals with "secret prior art" – *i.e.*, "an application for patent" – unlike §§ 102(a) and 102(b). A critical initial inquiry in determining whether the instant rejection is proper, is the determination of the proper legal standard for measuring the sufficiency of a U.S. patent for anticipation under 35 U.S.C. § 102(e). Stated another way, an initial inquiry that needs to be answered is what is the effective § 102(e) date for Gorman for the currently claimed subject matter. The Applicant submits that the proper legal standard to be applied under § 102(e) is that articulated by the Supreme Court in *Alexander Milburn Co. v. Davis-Bournonville Co.*, 270 U.S. 390, 401 (1926), and the Court of Customs and Patent Appeals in *In re Wertheim and Mishkin*, 209 U.S.P.Q. 554 (C.C.P.A. 1981); namely, that a U.S. patent can anticipate under 35 U.S.C. § 102(e) as of a particular date only to the extent that there is a sufficient disclosure under 35 U.S.C. § 112, first paragraph, for the subject matter at issue (*i.e.*, the subject matter of the claims being rejected as being anticipated under §102(e) by the patent).

For example, in *Wertheim*, the court addressed the specific question of the effective date of *a claimed invention* – for prior art purposes – to be given to a patent under §§ 102(e)/103

[1] The Applicant, by this argument, does not present for consideration by the Examiner the question of whether or not the subject matter *actually claimed* in the Gorman patent is supported within the meaning of § 112, first paragraph. The subject matter at issue (*i.e.*, that being claimed in the present application) is *not claimed* in Gorman.

where the application on which the patent issued added new matter to the original application upon which it was based and wished to claim the benefit of that earlier application under § 120. The court held that the § 102(e) effective date of the patent was limited to that subject matter in the patent (*i.e.*, either in its priority document or in the patent specification itself) that could satisfy the requirements of § 112, first paragraph, relative to the claims being rejected. *Wertheim*, 541 F.2d at 537, 209 U.S.P.Q. at 564 (C.C.P.A. 1981). The court recognized that a patent should be entitled to prior art effect under § 102(e) *only as to subject matter that was disclosed in a manner that would be sufficient under § 112, first paragraph*, because it was concerned that the secret prior art doctrine would otherwise be extended beyond logic. *Id.* ("We will extend the 'secret prior art' doctrine of *Milburn* .... only as far as we are required to do so by logic of those cases.").

The decision in *In re Schoenwald*, 964 F.2d 1122, 22 U.S.P.Q.2d 1671 (Fed. Cir. 1992), cannot be used to contravene the Supreme Court's requirements in *Alexander Milburn* and the Court of Customs and Patent Appeals' decision in *Wertheim*. *Schoenwald* involved a reference that qualified as prior art under § 102(b), not § 102(e). *See Schoenwald*, 964 F.2d at 1122, 22 U.S.P.Q.2d at 1672. As noted above, § 102(e) concerns an "application for patent" which is secret prior art, whereas § 102(b) concerns information that was in the public's hand more than one year before the date of the application for patent in the United States. 35 U.S.C. §§ 102(b) and 102(e). Thus, while *Schoenwald* may stand for the proposition that in order to qualify as anticipatory prior art under § 102(b) a reference need not disclose how to use the subject matter at issue sufficient to meet 35 U.S.C. § 112, first paragraph, it does not answer the question at issue here of the appropriate effective filing date of a § 102(e) reference.

In the present case, for a patent to have issued to Gorman on the subject matter in dispute here, *i.e.*, the pharmaceutical compositions and kits comprising, *inter alia*, an antagonist antibody which binds to IL-17E, the Gorman application must have described how to make and use that subject matter in a manner sufficient to meet the requirements of § 112. If it does not, no patent could have issued and, thus, the Gorman patent cannot be prior art as of its filing date for that subject matter. As discussed below, Gorman does not support, under § 112, the presently claimed subject matter and therefore is not a proper § 102(e) reference.

B. Gorman does not teach a specific, substantial, and credible utility for a pharmaceutical composition or kit containing, *inter alia*, an antagonist antibody and, therefore, cannot be applied under § 102(e).

The pharmaceutical compositions and kits of the rejected claims comprise, *inter alia*, antagonist antibodies that bind the polypeptide of SEQ ID NO:6 (which is referred to as IL-174 in Gorman). Therefore, in order to be a proper reference under § 102(e), Gorman must teach, among other things, a specific, substantial and credible utility for such an antibody. The term "antagonist" is defined in the instant application as including "any molecule that partially or fully blocks, inhibits, or neutralizes a biological activity" of a particular substrate. Application, p. 28, line 37 – p. 29, line 1. As will be discussed below, there is no teaching in Gorman specific to the human IL-174 polypeptide that would allow one of ordinary skill in the art to determine what function the IL-174 polypeptide exhibits, what the binding partner of that polypeptide is and, therefore, whether an antibody raised to IL-174 could act as an antagonist. Therefore, Gorman fails to provide a specific, substantial, and credible utility for the pharmaceutical compositions and kits of claims 72, 75, and 85 that contain, *inter alia*, antagonist antibodies that bind to the polypeptide of SEQ ID NO:6 as follows.

Gorman first suggests that the IL-170 family of cytokines is "likely to have similar or related biological activities [to IL-17]," predicated on Gorman's assertion that that the IL-170 family members "exhibit significant sequence similarity to the cytokine designated CTLA-8."[2] Gorman, col. 6, line 66 – col. 7, line 11. The family members of IL-170 that Gorman discloses are IL-171 through IL-177. *See e.g.*, Gorman, col. 6, lines 25-31. However, not only is Gorman's sequence similarity assertion not borne out with regard to human IL-174, in pleiotropic molecules like cytokines, one of ordinary skill in the art would recognize that primary sequence homology/identity is typically not a good predictor of function. Indeed, the Applicant has disclosed the results of experiments that show Gorman's speculation as to function of its IL-170 family members to IL-17 cannot be applied as a general rule to its identified family members. Figure 32A in the instant application, for example, shows a comparison of IL-17 and IL-17E (human IL-174 of Gorman) binding to the IL-17R and IL-17Rh1 receptors. That figure

[2] CTLA-8 is also more commonly identified as IL-17. *See generally*, Gorman, col. 6, line 59. Thus, the Applicant will refer to IL-17 rather than CTLA-8.

clearly shows that IL-17 preferentially binds to the IL-17R receptor while IL-17E preferentially binds to the IL-17Rh1 receptor. Figure 32B shows the relative abilities of IL-17 and IL-17E to bind to the IL-17Rh1 receptor. Based on those figures, one of ordinary skill in the art can readily determine that IL-17 does not bind, and IL-17E binds strongly to the IL-17Rh1 receptor. Consequently, given at least the differing receptor binding profile between IL-17 and IL-17E (human IL-174 of Gorman), one of skill in the art would not assume similar activities for those polypeptides based merely on primary sequence similarity. Any basis for such an assumption is further eroded by Gorman's failure to provide any experimental data to support its structural based prediction of a "similar biological activity" for human IL-174.

With respect to Gorman's assertion of sequence similarity between human IL-174 and IL-17, an analysis of the alignment of human IL-17 and human IL-174 polypeptides provided in Table 7 of Gorman using the BLAST local alignment tool, available on the National Center for Biotechnology Information website, reveals that there is only 29% identity between those two sequences. *See* Exhibit A. This comparison also undercuts Gorman's assertion in the specification that the nucleotide and amino acid sequences identified in its disclosure for the IL-170 family members each "exhibit significant sequence similarity to the cytokine designated CTLA-8." Gorman, col. 1, line 65 – col. 2, line 2. Moreover, Gorman states that only some members of the IL-170 family have a cystine knot motif in its cDNA sequence, which is the only feature Gorman identified as relating its IL-170 members to a cytokine related to TGF-β. Gorman, col. 6, lines 25-47. And human IL-174 is not listed among the certain family members that Gorman says have this structural feature. This, too, undercuts Gorman's assertion in the specification that the nucleotide and amino acid sequences identified in its disclosure for the IL-170 family members each "exhibit significant sequence similarity to the cytokine designated CTLA-8."

Thus, even though Gorman notes that purified IL-17 induces the secretion of IL-6 from synoviocytes, which is reversed by addition of antibodies, and that certain other cells "exhibit response to treatment with [IL-17]," from which it is surmised that IL-17 may play a role in inflammatory fibrosis, carcinomas, and other cancer cells (Gorman, col. 6, line 66 – col. 7, line

11), there is no reasonable basis provided in the specification for concluding that human IL-174 is "likely to have similar or related biological activities."

In addition to the foregoing, the tissue distribution information in Gorman fails to teach a specific, substantial, and credible utility for an antagonist antibody to the disclosed human IL-174 polypeptide. In fact, Gorman does not disclose any tissue distribution analysis specific to human IL-174. Although the Gorman disclosure reveals the distribution of human IL-171, IL-172, IL-173, and IL-175, it only discusses the distribution of the murine form of IL-174 in a general sense, without any supporting data, by stating that the "gene appears to be quite rare, which suggests the expression distribution would be highly restricted." Gorman, col. 53, lines 64-67. One of ordinary skill in the art could not surmise a specific use for human IL-174, or an antagonist antibody to it, based on such a general teaching.

Furthermore, the disclosure of Gorman provides no information regarding how to determine whether an isolated antibody to IL-174 would partially or fully block, inhibit, or neutralize a biological activity of human IL-174, in view of the fact that Gorman does not identify, for example, the receptor or receptors that actually bind to the human IL-174 polypeptide. In fact, Gorman does not identify any receptors for any of the so-called IL-170 family of cytokines, including IL-17. Gorman instead obligates the reader to perform the experiments necessary to identify receptors for each of the IL-170 family of cytokines, including the "screening of an expression library made from a cell line which expresses *potential* IL-170 receptors." Gorman, col. 54, lines 41-43 (emphasis added). There is no inkling of a suggestion in the Gorman disclosure as to the identity of the receptor(s) for any of the IL-170 family members, including the human IL-174 polypeptide.

Gorman also lacks a specific disclosure of a biological activity for human IL-174. While Gorman postulates that IL-17 "may be implicated in inflammatory fibrosis, e.g., psoriasis, scleroderma, lung fibrosis, or cirrhosis" (Gorman, col. 7, lines 4-6), and surmises that the IL-170 cytokines "are likely to have similar or related biological activities," for the numerous reasons outlined above, such conjectures are unfounded. Any implication that human IL-174, or any of the other IL-170 cytokines, is implicated in any of the aforementioned disease states would be

meaningless to one of ordinary skill in the art, as there is simply a lack of experimental data disclosed in Gorman to support such conjecture.

In sum, Gorman fails to provide any specific utility for an antagonist antibody to the IL-174 molecule because, as described above, it fails to provide any credible scientific evidence regarding the activity of IL-174 and/or its binding partner. *See, e.g., In re Fisher*, 421 F.3d 1365, 76 U.S.P.Q.2d 1225 (Fed. Cir. 2005) (holding that claims to nucleic acid sequences for which the corresponding biological function is unknown fail to satisfy the utility requirements). Because of the failure of Gorman to teach a specific utility for antagonist antibodies of IL-174 (and therefore the pharmaceutical compositions and kits containing such antagonist antibodies), the Applicant contends that Gorman does not satisfy the "how to use" prong of the § 112 requirements. Accordingly, under *Alexander Milburn* and *In re Wertheim*, Gorman is not entitled to the prior art effect of its application filing date under § 102(e) for claims 72, 75, and 85 that require functional antibodies and, thus, cannot anticipate those claims under § 102(e). In light of the foregoing, it is respectfully submitted that the § 102(e) rejection over Gorman should be withdrawn and claims 72, 75, and 85 passed to issue.

Based on substantial precedent, if Gorman fails to satisfy § 101 for the presently claimed subject matter, it also fails to meet the requirements of § 112, first paragraph. *See, e.g., In re Ziegler*, 992 F.2d 1197, 26 U.S.P.Q.2d 1600 (Fed. Cir. 1993), *In re Brana*, 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995), and *In re Fouche*, 439 F.2d 1237, 169 U.S.P.Q. 429 (C.C.P.A. 1971). In particular, the insufficient disclosure in Gorman regarding a specific utility for the IL-174 antagonist antibodies makes it impossible for Gorman to satisfy the "how to use" prong of § 112 for the presently claimed pharmaceutical compositions and kits containing those antibodies. As a matter of law, then, because Gorman fails to satisfy the requirements of § 101, it fails to provide an enabling disclosure under § 112 and cannot anticipate the appealed claims under § 102(e).

C. Gorman does not teach how to make a pharmaceutical composition or kit containing, *inter alia*, an antagonist antibody that binds to the polypeptide of SEQ ID NO:6 and, therefore, cannot be applied under § 102(e).

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the claimed invention without undue experimentation. *See, e.g., In re Wands*, 858 F.2d 731, 736-37, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988).

As discussed above, Gorman fails to provide any experimental data regarding the IL-174 polypeptide from which one of ordinary skill in the art could discern a specific biological activity for the polypeptide or disease state in which IL-174 plays a role. It merely speculates, based on low sequence homology to another cytokine (*i.e.*, 29% sequence homology to IL-17), that it is "likely to have similar or related biological activities" to that cytokine. Gorman provides no biological data, however, to support the assertion that IL-174 and IL-17 have similar and related activities. Gorman also fails to disclose any information regarding the binding partner of IL-174.

The Applicant asserts that without knowledge regarding an actual biological function or ligand/receptor binding profile for the underlying antigen (*i.e.*, in this case IL-174), one of ordinary skill in the art could not make an antagonist antibody to the IL-174 polypeptide. At a minimum, there would be no way for one of ordinary skill in the art, lacking such knowledge, to discern antibodies that antagonize the biological activity of IL-174 from other antibodies that do not exhibit that function. Accordingly, because Gorman does not disclose even the minimal information necessary to determine whether an antibody acts as an antagonist of IL-174, it would not have taught one of ordinary skill in the art how to make a pharmaceutical composition or kit containing such an antibody without undue experimentation. Gorman, therefore, fails to meet the § 112 enablement requirement. In view of the foregoing, the Applicant contends that Gorman cannot be properly applied against the claims under § 102(e).

For the sake of argument, even assuming the Examiner is applying the proper legal standard under § 102(e), in order for any reference to be anticipatory, it must enable one of ordinary skill in the art to make the claimed subject matter. For the reasons provided above, Gorman would not have enabled one of ordinary skill in the art to make a pharmaceutical

composition or kit containing, *inter alia,* an antagonist antibody that binds to the polypeptide of SEQ ID NO:6. Accordingly, the anticipation rejection of claims 72, 75, and 85 over Gorman is improper and should be withdrawn.

D. Gorman does not show its inventors were in possession of a pharmaceutical composition or kit containing, *inter alia,* an antagonist antibody that binds to the polypeptide of SEQ ID NO:6 and, therefore, cannot be applied under § 102(e).

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail so that one of ordinary skill in the art can reasonably conclude that the inventor had possession of the claimed invention. *See, e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991). Although the subject matter of the invention does not need to be described to exacting detail, "the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." *Id.* (citing *In re Gosteli,* 872 F.2d 1008, 1012, 10 U.S.P.Q.2d 1614, 1618 (Fed.Cir. 1989)).

As discussed above, Gorman fails to provide any experimental data regarding the human IL-174 polypeptide from which one of ordinary skill in the art could discern a specific biological activity for the polypeptide or disease state in which human IL-174 plays a role. It merely speculates, based on low sequence homology to another cytokine (*i.e.*, 29% sequence homology to IL-17), that it is "likely to have similar or related biological activities" to that cytokine. Gorman provides no biological data, however, to support the assertion that human IL-174 and IL-17 have similar and related activities. Gorman also fails to disclose any information regarding the binding partner of human IL-174. Without such specific disclosures, it is not possible for one of ordinary skill in the art to isolate antibodies that antagonize the biological activity of human IL-174 from other antibodies to human IL-174 that do not exhibit that antagonistic function.

Because Gorman does not disclose information necessary to determine whether an antibody acts as an antagonist of human IL-174, in view of the lack of specific disclosures regarding a biological activity, function, or ligand/receptor binding profile for the underlying

antigen (*i.e.*, human IL-174), one of ordinary skill in the art would not have considered the Gorman inventors to be in possession of a pharmaceutical composition or kit containing an antagonist antibody to the human IL-174 polypeptide. Accordingly, Gorman fails to meet the § 112 written description requirement. In view of the foregoing, the Applicant contends that Gorman cannot be properly applied against the claims under § 102(e).

For the reasons discussed in sections B through D above, Gorman does not satisfy the how-to-use prong of § 112, nor does it comply with the enablement or the written description requirement of § 112. Accordingly, applying the proper legal standard as detailed in Section A, Gorman cannot anticipate pending claims 72, 75, and 85 under § 102(e). It is respectfully submitted, therefore, that the § 102(e) rejection over Gorman should be withdrawn and the pending claims passed to issue.

In light of the above amendments and remarks, the Applicant believes that this application is now in condition for immediate allowance and respectfully requests that this case pass to issue.

The Examiner is invited to contact the undersigned at (202) 736-8157 if any issues may be resolved in that manner.

Respectfully submitted,

Date: September 17, 2007

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